

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1 to 3, 5 to 16, and 21 to 24 are pending with entry of this amendment. Claims 4 and 17 to 20 are cancelled. Claims 1, 21 and 23 are amended herein. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

With respect to claim 1, support for the general formula and indications can be found throughout the specification. For example, regarding the general formula and pyridinyl group, see specification at paragraphs 12, 60 to 79; Table 1 and original claim 22. Regarding the indications for treatment, see, e.g., paragraphs 111 to 116.

With respect to claim 21, the amendment merely adjusts dependency and the focus of the R group. Support can be found, e.g., in paragraphs 60 to 65 and original claims.

With respect to claim 23, the claim is merely narrowed and converted into a dependent claim.

Applicants note that the present amendments are based on claims recently issued in a sister European case Method of Immunomodulation Using Thione-Forming Disulfides (EPO# 02705749.6-2123 based on the same specification in PCT/US02/00795).

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

35 U.S.C. §102.

Claims 1, 2, 5, 6, 10 to 12, and 20 to 24 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Grasseti (U.S. 4,378,364), as evidenced by Barber (5,662,896) and Tagawa (Current Pharm. Design 6:681 (2000)). To the extent the rejection is deemed applicable to the amended claims, Applicants traverse.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. That is, in order for a reference to anticipate an invention, anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." *Kalman v. Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983).

Grassetti '364 (same deceased inventor of the present application) administered thione-forming disulfides (TFDs) to cancer patients to improve their "general physical condition" and improve "their feeling of well-being". See, e.g., column 4, line 61. The current rejections require that this administration of TFDs both inherently identified and inherently treated an individual in need of immune response modulation. There is no suggestion of a use of TFDs outside of the realm of pain reduction and improved mental well-being. No patients treated in Grassetti '364 had any of the ailments listed in the present claims. Therefore, the claims are novel.

35 U.S.C. §103(a).

Claims 1, 2, 5, 6, 10 to 12, and 20 to 24 were rejected under 35 U.S.C. §103(a) as allegedly obvious based on Grassetti (U.S. 4,378,364), in light of Oliver (Cancer Surveys, 13:173-204, 1992) and Tagawa (Current Pharm Design 6:681, 2000). To the extent the rejection is deemed applicable to the amended claims, Applicants traverse.

A proper analysis under the recently reaffirmed *Graham v. John Deere* standard demonstrates the non-obviousness of the invention. According to the Supreme Court in *KSR International Co v. Teleflex* (550 U.S. 398 (2007); 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385-1396 (US 2007)), the appropriate standard for analyzing questions of obviousness is that:

the scope and content of the prior art are determined, differences between the prior art and the claims at issue are analyzed and the level of ordinary skill in the pertinent art is resolved. Against this background the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc. might be utilized to give light to the circumstances surrounding the origin of the subject matter to be patented.

Id. quoting *Graham v. John Deere of Kansas City*, 383 U.S. 1, 17-18 (1966).

The current Examination Guidelines (e.g., MPEP 2143) and KSR require the Office in an obviousness rejection to provide a statement as to why one of skill would have combined known elements. Further, an obviousness rejection must include fact-based findings demonstrating: 1) a combination of reference elements describing each limitation of the claims, 2) known elements that function in the same way in the combination as in the references themselves, 3) the elements are combined by known methods, 4) the result of the suggested combination of elements would have been predictable, and 5) one of skill in the art would have expected success in providing the claim in light of the references. Here, the rejection fails each of these requirements, as applied to the Graham factors. Further, KSR requires that the Office should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."

As noted above, the primary Grassetti '364 reference does not provide all limitations of the present claims. The additional Oliver and Tagawa references do not cure this defect.

The TFDs in Grassetti are not taught functioning in the same way as those of the claims. Again this is not cured by the secondary references. Therefore, according to KSR, the claims are not obvious.

Based on the teachings of the cited references, one of skill would have had no expectation that TFDs would be useful for treatment of the indications in the claims. For example, one of skill in the art would not have expected a mood enhancer to successfully treat a mycosis.

Because the cited references do not render obvious the presently amended claims, Applicants respectfully request withdrawal of the rejections.

CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 769-3510 to schedule an interview.

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Respectfully submitted,

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Attachments:

- 1) Request for continued examination
- 2) An Information Disclosure Statement;
- 3) PTO-1449 Form; and;
- 4) 5 references.